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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,603	12/19/2001	Napoleone Ferrara	GENENT.1516CP1	4344
7590 09/13/2004 DENISE M. KETTELBERGER, Ph.D P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER HUYNH, PHUONG N	
			ART UNIT 1644	PAPER NUMBER
DATE MAILED: 09/13/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,603

Applicant(s)

FERRARA ET AL.

Examiner

Phuong Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58,62 and 80-104 is/are pending in the application.
- 4a) Of the above claim(s) 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 62,80-84,88,91-99,103 and 104 is/are rejected.
- 7) ☒ Claim(s) 85-87,89,90 and 100-102 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 58, 62, and 80-104 are pending.
2. Claim 58 stands withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.
3. Claims 62 and 82-104 are being acted upon in this Office Action.
4. In view of the amendment filed 6/1/4, the following objection and rejections remain.
5. The disclosure stands objected to because of the following informalities: (1) "Figures 11A-B" on page 9, line 23 does not match with the actual drawing (Figure 10A-C). It should be "Figure 10A-C"; (2) "Figure 20A-P" on page 12, line 19 should have been "Figure 20A-Q". (3) "F(ab \square)₂" on page 74, line 5 should have been "(Fab')₂". Appropriate action is required. It is noted that applicant attempts to amend the specification on 6/1/04. However, The amendment to the Brief description of the Drawing "Figures 10A-B" on page 9, line 23 and "Figures 20A-Q" on page 12, line 19 is still incorrect. The correction is "Figures 10A-C" and "Figures 20A-Q", respectively.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 62, 80-84, 88, 91-92, 94-99, 103 and 104 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for (1) an antibody or antibody fragment that specifically binds to EG-VEGF comprising an amino acid sequence of SEQ ID NO: 2, (2) a monoclonal antibody produced from hybridoma cells having ATCC accession number PTA-4119, PTA-4120, PTA-4121 or PTA-4122, (3) The said antibody or antibody fragment wherein the antibody or antibody fragment is a monoclonal antibody, a chimeric antibody or a humanized antibody and fragment thereof, (4) A composition comprising said antibody or antibody fragment mentioned above and a pharmaceutically acceptable carrier, (5) A kit or article

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of manufacture comprising a container; a label on the container, and the composition comprising the antibody or antibody fragment that specifically binds to EG-VEGF comprising an amino acid sequence of SEQ ID NO: 2, or a monoclonal antibody produced from hybridoma cells having ATCC accession number PTA-4119, PTA-4120, PTA-4121 or PTA-4122, **does not** reasonably provide enablement for (1) *all* antagonist of VEGF-VEGF that inhibits EG-VEGF induced proliferation of adrenal cortex-derived endothelial cells, (2) *any* antibody or antibody fragment (claim 80) such as monoclonal antibody (claim 81), chimeric antibody (claim 82), humanized antibody (Claim 83) and fragment thereof such as Fab, Fab', F(ab')₂ or Fv fragment (claims 81-84) that specifically binds to *all* EG-VEGF (claim 80) such as any native sequence EG-VEGF (claim 91), any human EG-VEGF human sequence (claim 92), (3) *any* antibody or antibody fragment that specifically binds to *all* EG-VEGF wherein the antibody or antibody fragment inhibits EG-VEGF induced proliferation of endothelial cells (Claim 88), (4) any composition comprising *any* antibody or antibody fragment that specifically binds to *all* EG-VEGF (claims 94-99 and 103) and (5) any article of manufacture comprising a container, a label on the container, and said composition (claim 104). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only four monoclonal antibodies 1C6, 2A3, 2A8 and 4H9 that bind specifically to human EG-VEGF comprising SEQ ID NO: 2 as shown in Figure 21 for diagnostic assays. The specification further discloses that only monoclonal antibodies 1C6 and 4H9 have neutralizing activity in cell-based proliferation assays (See Figure 21, see error bar).

The specification does not teach how to make all antagonist of EG-VEGF without the structure, i.e. amino acid sequence. The specification does not teach how to make all antibody and antibody fragment thereof mentioned above that bind to all "EG-VEGF", native sequence of

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any EG-VEGF such as human VEGF without the amino acid sequence. Further, there is insufficient guidance as to the binding specificity of all antibodies, let alone which epitope to which the antibody binds would result in antagonistic activity to all EG-VEGF.

Stryer *et al*, of record, teach that a protein is highly dependent on the overall structure of the protein itself and that the primary amino acid sequence determines the conformation of the protein (See enclosed appropriate pages).

Ngo *et al*, of record, teach that the amino acid positions within the polypeptide/protein that can tolerate change such as conservative substitution or no substitution, addition or deletion which are critical to maintain the protein's structure/function will require guidance (See Ngo *et al*, 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495).

Kuby *et al*, of record, teach that antibody epitopes (B cell epitopes) are not linear and are comprised of complex three-dimensional array of scattered residues which will fold into specific conformation that contribute to binding (See Kuby 1994, page 94, in particular). Immunization with a peptide fragment derived from a full-length polypeptide may result in **antibody specificity** that differs from the antibody specificity directed against the native full-length polypeptide.

Abaza *et al* teach that even a single amino acid substitution outside the antigenic site can exert drastic effects on the reactivity of a protein with monoclonal antibody against the site (See abstract, in particular).

Without the amino acid sequence of all EG-VEGF, it is unpredictable which undisclosed native sequence of all EG-VEGF would produce antibody that binds specifically to the undisclosed EG-VEGF, let alone having antagonistic activity to EG-VEGF induced proliferation of endothelial cells. Further, there is a lack of *in vivo* working example demonstrating *any* composition mentioned above are effective for treating *any* disease such as diabetes, infertility, polycystic ovary syndrome, or cancer. Since the EG-VEGF amino acid sequence and the binding specificity of the claimed antibody are not enabled, it follows that any antibody fragment, chimeric antibody, humanized antibody, and binding fragment thereof are not enabled. It also follows that any composition and article of manufacture comprising any undisclosed antibody mentioned above are not enabled.

Fogarty *et al*, of record, teach targeting angiogenesis using VEGF antagonist is a promising anticancer approach, however, the twelve recent failures in clinical trials using VEGF antagonist, indicate the unpredictability of angiogenesis inhibitors for cancer treatment.

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For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of *Ex parte Aggarwal*, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

Applicants' arguments filed 6/1/04 have been fully considered but are not found persuasive.

Applicants' position is that the specification containing sufficient disclosure to enable production of specific antibodies raised against specific antigens. Example 7 describes production of antibodies that specifically bind EG-VEGF of amino acid sequence (SEQ ID NO:2). The specification further discloses antibodies 1C6, 2M, 2A8, and 4119. Figure 21 clearly shows that antibodies 2A3 and 2A.8 have neutralized EG-VEGF activity. The claims under examination are drawn to antibodies that specifically bind EG-VEGF, and not methods of treating cancer with anti-EG-VEGF antibodies. The VEGF antagonist antibody AVSTINTM was recently approved by the FDA for the treatment of cancer (see enclosed press release). The USPTO has acknowledged that production of antibodies against a characterized antigen is a well developed and mature technology where the level of skill is high and advanced (see, for examples Example 16 of the Revised Written Description Guidelines training materials). Considering the high and advanced level of skill in the art and the guidance and working examples provided in the specification, Applicants assert one of skill in the art would be able to make and use the antibodies and compositions as claimed without undue experimentation.

However, the scope of the claims encompass all antagonist to any EG-VEGF, all antibody or antibody fragment (claim 80) such as monoclonal antibody (claim 81), chimeric antibody (claim 82), humanized antibody (Claim 83) and fragment thereof such as Fab, Fab', F(ab')₂ or Fv fragment (claims 81-84) that specifically binds to *all* EG-VEGF (claim 80) such as any native sequence EG-VEGF (claim 91), any human EG-VEGF human sequence (claim 92), (3) *any* antibody or antibody fragment that specifically binds to *all* EG-VEGF wherein the antibody or antibody fragment inhibits EG-VEGF induced proliferation of endothelial cells

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(Claim 88), (4) any composition comprising *any* antibody or antibody fragment that specifically binds to *all* EG-VEGF (claims 94-99 and 103) and (5) any article of manufacture comprising a container, a label on the container, and said composition (claim 104).

The specification discloses only four monoclonal antibodies 1C6, 2A3, 2A8 and 4H9 that bind specifically to human EG-VEGF comprising SEQ ID NO: 2 as shown in Figure 21 for diagnostic assays. The specification further discloses that only monoclonal antibodies 1C6 and 4H9 have neutralizing activity in cell-based proliferation assays (See Figure 21, see error bar).

The specification does not teach how to make *all* antagonist of EG-VEGF without the structure, i.e. amino acid sequence. The specification does not teach how to make all antibody and antibody fragment thereof mentioned above that bind to *all* "EG-VEGF", all native sequence of all EG-VEGF without the amino acid sequence. Further, there is insufficient guidance as to the binding specificity of all antibodies, let alone which epitope to which the antibody binds would result in antagonistic activity to all EG-VEGF. Until all the EG-VEGF sequence or native sequence of all EG-VEGF have been disclosed, one of skill in the art cannot make, much less how to use the claimed antibody.

8. Claims 62, 80-84, 88, 91-92, 94-99, 103 and 104 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of (1) *all* antagonist of VEGF-VEGF that inhibits EG-VEGF induced proliferation of adrenal cortex-derived endothelial cells, (2) *any* antibody or antibody fragment (claim 80) such as monoclonal antibody (claim 81), chimeric antibody (claim 82), humanized antibody (Claim 83) and fragment thereof such as Fab, Fab', F(ab')₂ or Fv fragment (claims 81-84) that specifically binds to *all* EG-VEGF (claim 80) such as any native sequence EG-VEGF (claim 91), any human EG-VEGF human sequence (claim 92), (3) *any* antibody or antibody fragment that specifically binds to *all* EG-VEGF wherein the antibody or antibody fragment inhibits EG-VEGF induced proliferation of endothelial cells (Claim 88), (4) any composition comprising *any* antibody or antibody fragment that specifically binds to *all* EG-VEGF (claims 94-99 and 103) and (5) any article of manufacture comprising a container, a label on the container, and said composition (claim 104).

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The specification discloses only four monoclonal antibodies 1C6, 2A3, 2A8 and 4H9 that bind specifically to human EG-VEGF comprising SEQ ID NO: 2 as shown in Figure 21 for diagnostic assays. The specification further discloses that only monoclonal antibodies 1C6 and 4H9 have neutralizing activity in cell-based proliferation assays (See Figure 21, see error bar). Further, the specification discloses only one EG-VEGF from human comprising amino acid residues 1-105 of SEQ ID NO: 2.

With the exception of the specific monoclonal antibodies 1C6, 2A3, 2A8 and 4H9 that bind specifically to only human EG-VEGF comprising SEQ ID NO: 2, all antagonist of EG-VEGF, and native sequence of all EG-VEGF without the amino acid sequence to which the claimed antibody binds are not adequately described. Further, there is inadequate written description about the binding specificity of all antibodies such monoclonal, humanized, chimeric, and binding fragments thereof that bind to all EG-VEGF. Since the EG-VEGF amino acid sequence and the binding specificity of the claimed antibody are not adequately described, it follows that any antibody fragment, chimeric antibody, humanized antibody, and binding fragment thereof, any composition and article of manufacture comprising said undisclosed antibody and antibody fragment thereof mentioned above are not adequately described.

Given the lack of a written description of *any* additional representative species of "antagonist of EG-VEGF", and antibody that binds to human EG-VEGF comprising SEQ ID NO: 2, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co.* 43 USPQ2d 1398; *University of Rochester v. G.D. Searle & Co.*, 69 USPQ2d 1886 (CA FC2004).

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicants' arguments filed 6/1/04 have been fully considered but are not found persuasive.

Applicants' position is that the specification containing sufficient disclosure to enable production of specific antibodies raised against specific antigens. Example 7 describes production of antibodies that specifically bind EG-VEGF of amino acid sequence (SEQ ID NO:2). The specification further discloses antibodies 1C6, 2M, 2A8, and 4119. Figure 21 clearly

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shows that antibodies 2A3 and 2A.8 have neutralized EG-VEGF activity. The claims under examination are drawn to antibodies that specifically bind EG-VEGF, and not methods of treating cancer with anti-EG-VEGF antibodies. The VEGF antagonist antibody AVSTINTM was recently approved by the FDA for the treatment of cancer (see enclosed press release). The USPTO has acknowledged that production of antibodies against a characterized antigen is a well developed and mature technology where the level of skill is high and advanced (see, for examples Example 16 of the Revised Written Description Guidelines training materials). Applicants submit that the specification sufficiently complies with the written description requirement of 35 U.S.C. § 112 first paragraph.

However, the scope of the claims encompass all antagonist to any EG-VEGF, all antibody or antibody fragment (claim 80) such as monoclonal antibody (claim 81), chimeric antibody (claim 82), humanized antibody (Claim 83) and fragment thereof such as Fab, Fab', F(ab')₂ or Fv fragment (claims 81-84) that specifically binds to *all* EG-VEGF (claim 80) such as any native sequence EG-VEGF (claim 91), any human EG-VEGF human sequence (claim 92), (3) *any* antibody or antibody fragment that specifically binds to *all* EG-VEGF wherein the antibody or antibody fragment inhibits EG-VEGF induced proliferation of endothelial cells (Claim 88), (4) any composition comprising *any* antibody or antibody fragment that specifically binds to *all* EG-VEGF (claims 94-99 and 103) and (5) any article of manufacture comprising a container, a label on the container, and said composition (claim 104).

The specification discloses only four monoclonal antibodies 1C6, 2A3, 2A8 and 4H9 that bind specifically to human EG-VEGF comprising SEQ ID NO: 2 as shown in Figure 21 for diagnostic assays. The specification further discloses that only monoclonal antibodies 1C6 and 4H9 have neutralizing activity in cell-based proliferation assays (See Figure 21, see error bar). Further, the specification discloses only one EG-VEGF from human comprising amino acid residues 1-105 of SEQ ID NO: 2.

With the exception of the specific monoclonal antibodies 1C6, 2A3, 2A8 and 4H9 that bind specifically to only human EG-VEGF comprising SEQ ID NO: 2, all antagonist of EG-VEGF, and native sequence of all EG-VEGF without the amino acid sequence to which the claimed antibody binds are not adequately described. Further, there is inadequate written description about the binding specificity of all antibody such monoclonal, humanized, chimeric, and binding fragment thereof that bind to *all* EG-VEGF. Since the native sequence of all EG-VEGF and the binding specificity of the claimed antibody are not adequately described, it follows

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that any antibody fragment, chimeric antibody, humanized antibody, and binding fragment thereof, any composition and article of manufacture comprising said undisclosed antibody and antibody fragment thereof mentioned above are not adequately described. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116.). Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The native sequence of all EG-VEGF itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes v. Baird*, claims directed to mammalian FGF’s were found unpatentable due to lack of written description for the broad class.

Therefore, only antibody such as monoclonal, humanized, chimeric and fragment thereof that bind specifically to the isolated human EG-VEGF comprises SEQ ID NO: 2 but not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

9. The following new ground of rejections is necessitated by the amendment filed 6/1/04.
10. The filing date of the instant claims is deemed to be the filing date 9/7/2000 of provisional application 60/230,978. If applicant desires priority prior to 9/7/2000, applicant is invited to point out and provide documentary support (i.e. page and line number and sequence of EG-VEGF) for the priority of the instant claims in 60/213,637, PCT/US/00219, 60/145,698, US99/12252, and 60/096,146. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

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11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 62, 80-84, 88, 91-99, 103 and 104 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat No 6,485,938 B1 (filed November 16, 1999; PTO 892).

The '938 patent teaches various antibodies such as monoclonal (See col. 46, lines 52-62, in particular), humanized and chimeric antibody (See col. 48, lines 44-53, in particular) and binding fragment thereof such as F(ab')₂, Fab', Fv, scFv (see col. 47, lines 22-66, in particular) that binds to the native full-length human Zven comprising SEQ ID NO: 5 that has amino acid sequence 100% identical to the claimed amino acid sequence of SEQ ID NO: 2 (See SEQ ID NO: 5 of '938 patent, col. 51, line 13-14, in particular). The '938 patent further teaches a kit or article of manufacture comprising the reference antibody, a container and written instructions for using the reference antibody (See col. 54, lines 36-52, in particular). The '938 patent further teaches a composition comprising the reference antagonist antibody such as anti-Zven2 antibody and injectable solution (See col. 57, lines 22-36, in particular). Thus, the reference teachings anticipate the claimed invention.

13. Claims 85-87, 89-90, and 100-102 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

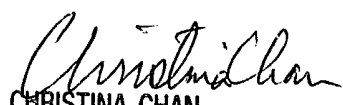
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.
16. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

September 3, 2004


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